

Date: 16-04-2015

Revision date: 15-Aug-23.

Issue: 1.1

This procedure is designed to test the BPM accuracy of a Viamed V1000 Foetal Heart Simulator (part number 1410000).

Introduction

The V1000 Foetal Heart Simulator allows the operation and functionality of foetal heart monitors to be assessed. It is a hand held, portable unit for use in any environment where foetal heart monitors need to be tested: before use, when suspected faulty or after routine servicing.

The V1000 simulates heart rates in the range of 30 BPM to 210 BPM. The V1000 is a simulator; it is not a calibration device, therefore during routine use it should not be used to validate the accuracy of an individual monitor's displayed foetal heart rate.

The V1000 cannot be used itself as a calibrator, as the algorithm of each manufacturer's type/models of foetal heart monitors is not disclosed to and cannot be verified by Viamed. The V1000 was designed for use by end users, not manufacturers. However, a manufacturer may wish to qualify a V1000 by comparison to one of their own calibrated reference foetal heart monitors. Then by using the reference method, should the manufacturer decide so, there is no reason why such a V1000 cannot be then used to assess heart rate readings of other foetal heart monitors of the same the model.

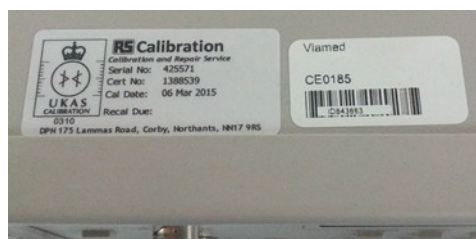
If a V1000 does not meet the specification or if performance is suspect, then the unit should be returned to Viamed for evaluation or repair. Note: The output BPM is governed by the firmware and the micro controller - there is no adjustable calibration control

Procedure

This procedure tests the period of the V1000 simulated signal at the heart rate settings: 60 – 210 bpm, the accepted tolerance of the readings is +/- 1%. The setting of 30 bpm has been omitted from the test since no current foetal heart monitor goes down as low as 30 bpm.

A Certificate of Calibration is to be issued with each new V1000, as customers may require a certificate as part of their ISO procedures. On a periodic basis customers may wish for a Certificate of Calibration to be reissued, i.e. annually. In such a situation a V1000 may be returned to Viamed for testing, using service part number 1480001.

NOTE: The readings of each V1000 are measured by calibrated test equipment, which in turn has calibration traceable to UKAS calibration standards.



COMPANY OPERATING PROCEDURE. VM3COP55.01

Foetal heart simulator BPM accuracy test

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Test equipment: **CE0185**

TF930 3 GHz Counter,
manufactured by Thurlby Thandar Instruments (Aim TTi).

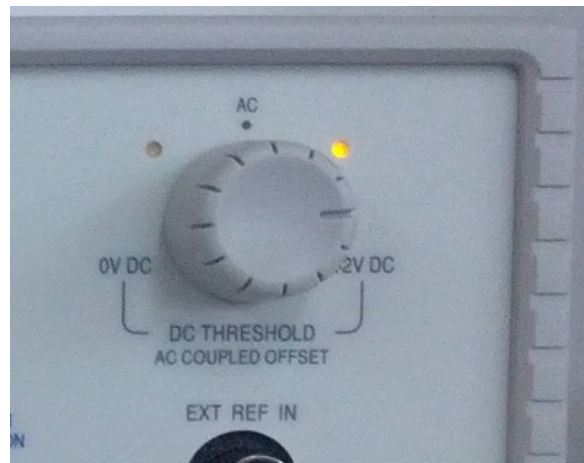
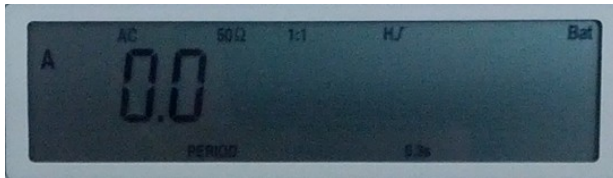
The Counter can be powered by mains or by the internal rechargeable battery.

To switch on press the **Operate** button. Once switched on change settings:

From **FREQUENCY** to **PERIOD**, by pressing the **PERIOD** button.

From **IMPEDANCE 1 MΩ** to **IMPEDANCE 50Ω**, press the button to toggle between each setting.

If not already done so, then attached an oscilloscope test probe to the input as shown, ensure that the attenuation on the test probe is set to **X1** and not to **X100**.



NOTE: Before proceeding with the testing ensure that you use an ESD wrist strap.

Open up the V1000 under test, insert batteries, switch on, select auto function. It is a good idea to set the V1000 intensity output to maximum, so that output can be clearly heard.

Attach test probe across connections pin 1 (gnd) & 5 (signal) as below.

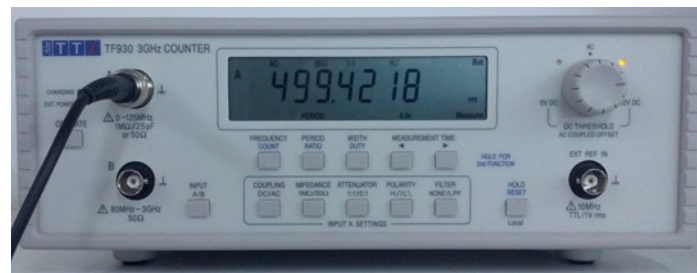
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If measured value is not displayed it may be necessary to slightly adjust the DC THRESHOLD/AC COUPLED OFFSET.



Example shows reading at 120 bpm, i.e. target value 500.00 ms.
Displayed measured reading to record = 499.42 ms.

Ignoring the 30 bpm setting, record the period values (to 2 d.p.) on the test sheet (copy attached, **Z drive/V1000 Calibration Certificates/V1000 Certificate of Calibration template without 30bpm**) and save in **Z drive/V1000 Calibration Certificates/Issued Certificates**, with file name adding the V1000 serial number and the test date as follows:

V1000 Certificate of Calibration for xxxxxxxxxx YYYY-MM-DD

On the test sheet record:

Certificate number (Obtain from Intrastats\Stock\Calibration Certificates\)

Serial number

Name

Date (format example: **16th April 2015**)

Once the form has been completed, print onto Viamed letter headed paper and over stamp the signature with the circular 'Viamed' blue ink stamp. Also upload a pdf of the completed form to Intrastats\Stock\Calibration Certificates\

The V1000 can now be reassembled.

Test the unit functions correctly using the operating instructions found in the user manual.

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